Kiwa Belgelendirme Hizmetleri A.Ş.
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10.03.2025

Notified Body Confirmation Letter Reference: MY-25-003392

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, Kiwa Belgelendirme Hizmetleri A.Ş Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1984 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Company Name*:* Schönn Medizintechnik GmbH

Address*:* Andreas-Bornes Str. 46, 41179 Mönchengladbach
SRN Number (if available)*:* DE-MF-000023078

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Mustafa Serkan Sevimli
Medical Devices Division Manager

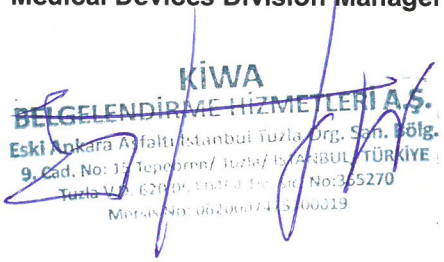

Table 1: Devices covered by this letter and for which the NB is ALSO responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the preapplication stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Medical Air Supply System	Class IIb	The MDR device is not a substitute device.	*Certificate #1; 1984-MDD-19-562 NB# 1984 Kiwa Belgelendirme Hizmetleri A.Ş.*
Medical Vacuum Supply System	Class IIa	The MDR device is not a substitute device.	*Certificate #1; 1984-MDD-19-562 NB# 1984 Kiwa Belgelendirme Hizmetleri A.Ş.*
Medical Compressed Gas Supply System	Class IIb	The MDR device is not a substitute device.	*Certificate #1; 1984-MDD-19-562 NB# 1984 Kiwa Belgelendirme*

			Hizmetleri A.Ş.
AGSS Supply System	**Class IIa**	**The MDR device is not a substitute device.**	*Certificate #1; 1984-MDD-19-562 NB# 1984 Kiwa Belgelendirme Hizmetleri A.Ş.*
Medical Copper Tubes and Fittings	**Class IIb**	**The MDR device is not a substitute device.**	*1984-MDD-19-562 NB# 1984 Kiwa Belgelendirme Hizmetleri A.Ş.*
Medical Gas Alarm Panel	**Class IIb**	**Medical Alarm Panels**	*1984-MDD-18-495 NB# 1984 Kiwa Belgelendirme Hizmetleri A.Ş.*
Zone Wall Units	**Class IIb**	**The MDR device is not a substitute device.**	*1984-MDD-19-562 NB# 1984 Kiwa Belgelendirme Hizmetleri A.Ş.*
Operational Room Surgical Control Panel	**Class IIa**	**The MDR device is not a substitute device.**	*1984-MDD-19-562 NB# 1984 Kiwa Belgelendirme Hizmetleri A.Ş.*
Medical Gas Terminal Units and Probes	**Class IIb**	**The MDR device is not a substitute device.**	*1984-MDD-19-562 NB# 1984 Kiwa Belgelendirme Hizmetleri A.Ş.*
Oxygen Flowmeters	**Class IIb**	**The MDR device is not a substitute device.**	*1984-MDD-19-562 NB# 1984 Kiwa Belgelendirme Hizmetleri A.Ş.*

Vacuum Regulators	**Class IIa**	**The MDR device is not a substitute device.**	***1984- MDD-19-562 NB# 1984 Kiwa Belgelendirme Hizmetleri A.Ş.***
Bed Head Units	**Class IIb**	**The MDR device is not a substitute device.**	***1984- MDD-19-562 NB# 1984 Kiwa Belgelendirme Hizmetleri A.Ş.***
Intensive Care Units	**Class IIb**	**The MDR device is not a substitute device.**	***Certificate #1; 1984- MDD-19-562 NB# 1984 Kiwa Belgelendirme Hizmetleri A.Ş.***
Pendants	**Class IIb**	**The MDR device is not a substitute device.**	***Certificate #1; 1984- MDD-19-562 NB# 1984 Kiwa Belgelendirme Hizmetleri A.Ş.***

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the preapplication stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
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Confirmation Letter Revision History

Date	Revision No	Action
10/03/2025	Rev00	Initial issue
01/07/2025	Rev01	The document has been revised exclusively in English